

§ 5.32b

27 CFR Ch. I (4–1–11 Edition)

(iii) The names “egg” and “peanuts”, as well as the names of the different types of tree nuts, may be expressed in either the singular or plural form, and the term “soy”, soybean”, or “soya” may be used instead of “soybeans”.

(b) *Voluntary labeling standards.* Major food allergens (defined in paragraph (a)(1) of this section) used in the production of a distilled spirit product may, on a voluntary basis, be declared on any label affixed to the container. However, if any one major food allergen is voluntarily declared, all major food allergens used in production of the distilled spirit product, including major food allergens used as fining or processing agents, must be declared, except when covered by a petition for exemption approved by the appropriate TTB officer under § 5.32b. The major food allergens declaration must consist of the word “Contains” followed by a colon and the name of the food source from which each major food allergen is derived (for example, “Contains: egg”).

(c) *Cross reference.* For mandatory labeling requirements applicable to distilled spirits products containing FD&C Yellow No. 5 and sulfites, see §§ 5.32(b)(5) and (7).

[T.D. TTB–53, 71 FR 42268, July 26, 2006]

§ 5.32b Petitions for exemption from major food allergen labeling.

(a) *Submission of petition.* Any person may petition the appropriate TTB officer to exempt a particular product or class of products from the labeling requirements of § 5.32a. The burden is on the petitioner to provide scientific evidence (including the analytical method used to produce the evidence) that demonstrates that the finished product or class of products, as derived by the method specified in the petition, either:

(1) Does not cause an allergic response that poses a risk to human health; or

(2) Does not contain allergenic protein derived from one of the foods identified in § 5.32a(a)(1)(i), even though a major food allergen was used in production.

(b) *Decision on petition.* TTB will approve or deny a petition for exemption submitted under paragraph (a) of this section in writing within 180 days of re-

ceipt of the petition. If TTB does not provide a written response to the petitioner within that 180-day period, the petition will be deemed denied, unless an extension of time for decision is mutually agreed upon by the appropriate TTB officer and the petitioner. TTB may confer with the Food and Drug Administration (FDA) on petitions for exemption, as appropriate and as FDA resources permit. TTB may require the submission of product samples and other additional information in support of a petition; however, unless required by TTB, the submission of samples or additional information by the petitioner after submission of the petition will be treated as the withdrawal of the initial petition and the submission of a new petition. An approval or denial under this section will constitute a final agency action.

(c) *Resubmission of a petition.* After a petition for exemption is denied under this section, the petitioner may resubmit the petition along with supporting materials for reconsideration at any time. TTB will treat this submission as a new petition for purposes of the time frames for decision set forth in paragraph (b) of this section.

(d) *Availability of information.*—(1) *General.* TTB will promptly post to its public Web site, <http://www.ttb.gov>, all petitions received under this section as well as TTB’s responses to those petitions. Any information submitted in support of the petition that is not posted to the TTB Web site will be available to the public pursuant to 5 U.S.C. 552, except where a request for confidential treatment is granted under paragraph (d)(2) of this section.

(2) *Requests for confidential treatment of business information.* A person who provides trade secrets or other commercial or financial information in connection with a petition for exemption under this section may request that TTB give confidential treatment to that information. A failure to request confidential treatment at the time the information in question is submitted to TTB will constitute a waiver of confidential treatment. A request for confidential treatment of information under this section must conform to the following standards:

(i) The request must be in writing;

(ii) The request must clearly identify the information to be kept confidential;

(iii) The request must relate to information that constitutes trade secrets or other confidential commercial or financial information regarding the business transactions of an interested person, the disclosure of which would cause substantial harm to the competitive position of that person;

(iv) The request must set forth the reasons why the information should not be disclosed, including the reasons the disclosure of the information would prejudice the competitive position of the interested person; and

(v) The request must be supported by a signed statement by the interested person, or by an authorized officer or employee of that person, certifying that the information in question is a trade secret or other confidential commercial or financial information and that the information is not already in the public domain.

[T.D. TTB-53, 71 FR 42268, July 26, 2006]

§ 5.33 Additional requirements.

(a) *Contrasting background.* Labels shall be so designed that the statements required by this subpart are readily legible under ordinary conditions, and such statements shall be on a contrasting background.

(b) *Location of statements and size of type.* (1) Statements required by this subpart, except brand names, shall appear generally parallel to the base on which the bottle rests as it is designed to be displayed or shall be otherwise equally conspicuous.

(2) Statements required by this subpart, except brand names and the declaration of sulfites in § 5.32(b)(7), shall be separate and apart from any other descriptive or explanatory matters.

(3) If not separate and apart from other descriptive or explanatory matter printed on the label, the statement declaring the presence of sulfites shall be of a size substantially more conspicuous than surrounding nonmandatory labeling information.

(4) Statements of the type of distilled spirits shall be as conspicuous as the statement of the class to which it refers, and in direct conjunction therewith.

(5) Statements required by this subpart, except brand names, shall be in script, type, or printing not smaller than 2 millimeters (or 8-point gothic until January 1, 1983), except that, in the case of labels on bottles of 200 milliliters or less capacity, such script, type, or printing shall not be smaller than 1 millimeter (or 6-point gothic until January 1, 1983).

(6) When net contents are stated either in metric measures or in both metric and U.S. fluid measures, statements required by the subpart, except brand names, shall be in script, type, or printing not smaller than 2 millimeters (or 8-point gothic until January 1, 1983), except that, in the case of labels on bottles of 200 milliliters or less capacity such script, type, or printing shall not be smaller than 1 millimeter (or 6-point gothic until January 1, 1983).

(c) *English language.* The requirements of this subpart shall be stated in the English language, except that the brand name need not be in English, and for products bottled for consumption within Puerto Rico the required information may be stated in the Spanish language if the net contents and, if the product is an imitation, the word "imitation" are also stated in the English language.

(d) *Location of label.* Labels shall not obscure government stamps or be obscured thereby. Labels shall not obscure any markings or information required to be permanently marked in the bottle by other U.S. Treasury Department regulations.

(e) *Labels firmly affixed.* Labels which are not an integral part of the bottle shall be affixed to bottles in such manner that they cannot be removed without thorough application of water or other solvents.

(f) *Additional information on labels.* Labels may contain information other than the mandatory label information required by this subpart if the information does not conflict with, or in any manner qualify, statements required by this part.

(g) *Contents of bottles.* A complete and accurate statement of the contents of the bottles to which labels are to be or have been affixed shall be submitted,